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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/509,449 03/28/00' ADYAGI

K 594.352USWO

EXAMINER
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HM22/0927

WORTMAN, D	
ART UNIT	PAPER NUMBER

1648  
DATE MAILED:

14  
09/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

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**Office Action Summary**

Application No.

09/509,449

Applicant(s)

AOYAGI ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 28 March 2000 and 14 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3/2
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Claims 3-6 were amended preliminarily. Claims 1-7 are pending and under examination.

Claims 1 and 6 are objected to because of the following informalities: Claims 1 and 6 recite the phrase "characterized by" which is not preferred in U.S. practice. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6, and 7 are confusing because each recites either "probe" or "probes" but the cited terminology is apparently not intended to mean the same thing each time it is used; i.e., it appears that in some claims "probe" is intended to refer to an antibody but in other claims "probe" is intended to mean an antigen. Applicant is requested to clarify the claim language by using consistent and clear terminology.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are at minimum, a "contacting" and a "detecting" step, which are required in order to define an immunoassay.

Claims 1 and 6 are also indefinite because each recites in the preamble "A method for measurement of ..." but does not recite language that would serve to

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correlate the results obtained in a last step with the purpose or goal of the claim as stated in the preamble, i.e., "measurement."

Claim 6 is indefinite because it recites "while also measuring anti-HCV antibodies"; it is not clear what is intended. For example, is it intended that both HCV antigen and HCV antibodies are to be measured in a sample at the same time, in the same reaction vessel, or at the same time, and from the same sample, but in parallel, separate reactions?

Claim 7 is indefinite in reciting "the probe" without clear antecedent in claim 6 which recites "probes."

Claim 7 is indefinite in reciting "an HCV-related polypeptide" because it is not clear what "related" means or how related a polypeptide must be in order to fall within the intended limitations of the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Aoyagi et al. (Journal of Clinical Microbiology 37(6):1802-1808, June 1999), cited on PTO 892, attached. Aoyagi et al. disclose an immunoassay method for detecting hepatitis C core antigen in the presence of Triton X-100, CHAPS, and SDS in a sample pretreated with the same composition, thus anticipating the subject matter of claims 1-5. (See, e.g.,

page 1803, column 1, "Specimen pretreatment and EIA for HCVcAg.") Aoyagi et al. disclose also measuring anti-HCV antibodies by their binding with HCV-related polypeptides. (See, e.g., page 1803, paragraph bridging column 1 and column 2, "EIA for anti-HCV core antibodies.")

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being anticipated by WO99/06836, cited on PTO 892, attached, and published 2/11/99. The Abstract discloses "a method for assaying a virus antigen and a virus antibody in the presence of a surfactant which has alkyl having 10 or more carbon atoms and a secondary, tertiary or quaternary amine and/or a nonionic surfactant on the basis of the bonds to the probes thereof," and HCV is disclosed in the body of the document, as well as the English version of the title ("Method for Detection or Measurement of Hepatitis C Virus") that appears at the beginning of the sequence listing, thus anticipating the subject matter of claims 1-7.

Applicant cannot rely upon the foreign priority papers to overcome these rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (Journal of General Virology 73:667-672, 1992), cited by Applicant on PTO 1449. Takahashi et al. disclose detection of HCV core antigen in the presence of the nonionic surfactant Tween 80 (see page 668, "ELISA for HCV core antigen").

Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kashiwakuma et al. (Journal of Immunological Methods 190:79-89, 1996), cited by

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Applicant on PTO 1449. Kashiwakuma et al. disclose detection of HCV core antigen in the presence of the nonionic surfactant Triton X-100 (see page 82, section 2.8, Detection of HCV core protein in serum by sandwich FEIA).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Masalova et al. (Journal of Medical Virology 55(1):1-6, May 1998), cited on PTO 892, attached. Masalova et al. disclose improved results in measurement of hepatitis C virus core antigen using samples treated with the anionic detergent SDS and nonionic surfactant Tween 80 or with Tween 80 only (see, e.g., page 4, paragraph bridging column 1 and column 2), thus anticipating the subject matter of claims 1-4.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-29 of copending Application No. 09/269897. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 22-29 are drawn to a method of detecting viral antigen in the presence of detergents or surfactants that

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encompasses the method of detecting HCV antigen in the presence of the same detergents or surfactants as claimed in instant claims 1-5. Although claims 22-29 of 09/269897 are broader than the instant claims, it is evident that detection of HCV antigen is encompassed because HCV is specifically recited in claims 28 and 29.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday 7:30-5:00 or on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
September 26, 2001